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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,871	09/28/2006	Walthard Vilser	GK-OEH-255/500814.20157	4625

26418 7590 10/20/2008
REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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10/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,871	Applicant(s) VILSER ET AL.	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/28/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 25-48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In addition to inquiry of whether a claimed method falls within a judicial exception, Supreme Court precedent (*Diamond vs. Diehr*, 450 U.S. 175, 184 (1981); *Parker vs. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).) and recent Federal Circuit decisions, require that a claim drawn to a process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. 101 and is improperly directed to non-statutory subject matter. Thus, to qualify as a 35 U.S.C. 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied or positively recite the subject matter that is being transformed. As claims 25-48 are not tied to another statutory class, nor do they positively recite subject matter being transformed, they are improperly directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 25-37, 40, 41 and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Beach et al.'017 (cited by Applicant).

Beach et al.'017 discloses a method for the spectral photometric determination of oxygen saturation of blood in optically accessible blood vessels, the method comprising: determining the intensity of the reflection of blood vessels and their vessel-free environment based on at least two spectrally different images and on an empirically determined relationship between the oxygen saturation and a ratio of the intensities of the reflection of the blood vessels and their vessel-free environment, wherein the determining step comprises illuminating the blood vessels and their environment simultaneously (physiological stimulation) with a measurement wavelength at which the reflection of oxygenated and reduced hemoglobin differs and illuminating the blood vessels with a reference wavelength at an isosbestic wavelength of hemoglobin (page 15, line 6 – page 17, line 8), and wherein the oxygen saturation is determined as a linear function of the quotient of the logarithmized reflection ratios in the vessel-free environment and on the blood vessel at the measurement wavelength and at the isosbestic wavelength, the slope and linear term of the linear function being empirically determined from readings at a plurality of blood vessels (page 23, line 12 – page 28, line 20); tuning every measurement wavelength and reference wavelength, respectively, to a color channel of a color camera used to record the images (page 15, line 6 – page 17, line 17); correcting dependencies of oxygen saturation on vessel diameter and pigmentation of the environment of the blood vessels by using correctives that are empirically determined, the correctives comprising a linear function of either the vessel diameter or pigmentation, wherein its slope and linear term are empirically determined (page 23, line 12 – page 28, line 20); and automatically, by image-processing means or manually, detecting the direction of the blood vessels and their vessel-free environment and taking an average over the reflection values of all the image points associated with the blood vessel, wherein specular reflections are identified and eliminated automatically (page 14, line 11 – page 28, line 20); and wherein the method also comprises a physiological stimulation

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brought about by inhalation of carbogen (which comprises oxygen) by the test subject (page 34, lines 14-25).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beach et al.'017, as applied to claim 37, further in view of Faubert et al.'247 (cited by Applicant).

Beach et al.'017 discloses all the elements of the current invention, as discussed in paragraph 4 above, except for the physiological provocation or stimulation being brought about by flicker light. While page 15, lines 6-11 of Beach et al.'017 disclose that flashes of light are supplied to the retina of the patient in order to make the oxygen saturation measurements, it fails to disclose the details of the flashes of light. Faubert et al.'247 teaches a method wherein stimulation to the retina in the form of flickering light is provided in order to obtain oxygenation levels of the patient (see ABSTRACT). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Beach et al.'017 to include using flickering light as the stimulating flashes to the retina, as taught by Faubert et al.'247, since Beach et al.'017 discloses that stimulating flashes of light are required, but fails to give the details of the flashes of light, and Faubert et al.'247 teaches that flickering light stimulation to the retina is a method capable of being used to determine oxygenation levels of a patient.

7. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beach et al.'017, as applied to claim 25, further in view of Cabib et al.'853 (cited by Applicant).

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Beach et al.'017 discloses all the elements of the current invention, as discussed in paragraph 4 above, except for an image being prepared of the structure of the blood vessel in which the oxygen saturation is coded or marked. Cabib et al.'853 teaches preparing an image of the structure of blood vessels in which oxygen saturation is coded or marked in order to enhance the distinction between different types of vessels (see Figure 14e and col. 40, lines 32-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Beach et al.'017 to include preparing an image of the structure of the blood vessels in which oxygen saturation is coded or marked, as taught by Cabib et al.'853, since it would enhance the distinction between different types of vessels.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/

Primary Examiner, Art Unit 3768